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Centers for Medicare and Medicaid Services

HCPCS Public Meeting Agenda for JUNE 22, 2005 SUPPLIES AND OTHER (DAY 2)

Please note that this agenda contains preliminary decisions and do not necessarily reflect what the final decisions will be. Preliminary decisions provide a basis for comment at public meetings. All coding changes, when finalized will be published by mid November on the CMS HCPCS website at www.cms.hhs.gov/medicare/hcpcs, and effective January 1, 2006 unless otherwise noted in the HCPCS Annual Update or on a Quarterly Update.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Each meeting day will begin at 9 a.m. and is scheduled to end at 5 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; or 5 minutes for "5-Minute Speakers"), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers are asked to please arrive prepared and wait until it is their turn to speak.

Meeting Agenda Item #1
June 22, 2005
HCPCS Request #05.04

Background/Discussion:

Lisa Burg of MED-TEC Inc. submitted a request to establish a code for implanted gold markers, trade name: Acculoc implanted gold localization markers. According to the requester, Acculoc implanted markers establish a permanent, accurate, internal reference system ensuring sub-millimeter localization accuracy at each delivery of radiation therapy dose. The markers show up distinctly on film, EPID, or CR images. These images are then brought into the Acculoc software, and 3D algorithms output the exact, sub-millimeter moves necessary to accurately position the patient, and the target, for high-precision radiotherapy dose delivery. This allows the radiation dose to be delivered to the tumor/target, sparing surrounding healthy tissue and critical structures.

CMS HCPCS Workgroup Preliminary Decision: Use existing CPT code as directed by insurer. Refer to the American Medical Association CPT editorial panel for inquiries related to the establishment of a new CPT code including markers used for precise targeting.

No insurer identified a national program operating need to alter the existing code set to identify a specific type of markers used for precise targeting of x-ray, used as part of a procedure. For guidance regarding appropriate coding of radiation therapy, including markers, contact the insurer in whose jurisdiction a claim would be filed. For Medicare OPPS, localization is packaged in various APCs, and not separately payable. For APCs, separate payment is not allowed for supplies. In a physician's office, unlisted surgical procedure CPT codes are available for various anatomic areas of the body. Payment is based on carrier pricing. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. The applicant is referred to the American Medical Association (AMA) CPT Editorial Panel for requests to establish a CPT code for insertion of radiologic markers for precise targeting in areas of the body for which CPT codes may not currently exist and for discussion of the valuation of the code and consideration of the markers in the practice expense.

Meeting Agenda Item #2
June 22, 2005
HCPCS Request #05.156

Background/Discussion:

Ken Lester of Millennial Medical Equipment, LLC submitted a request that CMS either assign existing code E0117 for use to identify the Millennial Crutch; or modify an existing code or create a new code to describe the unique features of Millennial Crutch and assign it "a reimbursement range that reflects its added value to the user over existing standard crutches". Existing code E0117 reads: "CRUTCH, UNDERARM, ARTICULATING SPRING ASSISTED, EACH". According to the requester, the Millennial Crutch operates the same way traditional crutches do. They are placed slightly below the armpit with the tip touching the ground in front of the user. Grasping the handle the user moves in a forward direction supporting his or her weight on the hands and arms and steps or swings taking the weight off of the involved leg. Millennial Crutch has a spring shock-absorbing/power assist feature which compresses as the crutch is planted ahead of the user, and as he or she steps through, releases the tension of the spring positively to help him or her propel forward. This requires less energy of the user than it would with conventional crutches. Millennial crutch is adjusted to the height of the user and to proper arm angle and gripping position. The crutch also detaches at the mid-section so that it can be collapsed or folded.

CMS HCPCS Workgroup Preliminary Decision: Use existing code E0116 Crutch, underarm, other than wood, adjustable or fixed, with pads, tips and handgrips.

An existing code, E0116, adequately describes a category of crutches which performs a function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. No insurer identified a national program operating need to alter the existing code set to separately identify this product. The item that is the subject of this request contains a shock absorber, and does not provide spring assistance, therefore, it is in appropriate to use code E0117 to identify this product. It is not within the jurisdiction of HCPCS code set maintainers to assign fees to codes. Any concerns or inquires regarding reimbursement rates should be submitted to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

Meeting Agenda Item #3
June 22, 2005
HCPCS Request #05.157

Background/Discussion:
Wayne Urban of LS Products LLC submitted a request to establish a code for a leg sling, trade name: Webb's Leg Sling. According to the requester, Webb's Leg Sling is a lightweight shoulder harness that suspends a patient's injured leg in a flexible position for patients using crutches or walkers. The harness is designed to keep weight off of one leg for the purpose of supporting a weak or injured foot or ankle in a physician ordered non-weight bearing circumstance. It functions by transferring the weight of the lower leg to the opposite shoulder using a harness made of durable, high strength, polypropylene webbing. Another similar harness is worn around the injured foot and ankle of the injured limb. An elastic mid-section connects the two harnesses near the hip area. The shoulder harness is adjustable in order to support the injured foot a few inches off the ground. The shoulder harness and shin/ankle cuff are padded for comfort and protection. According to the applicant, existing code A4565 "Slings" does not adequately describe this product, and A4565 " is an old code which describes cloth and canvas arm slings" and payment rates are inadequate to cover manufacturing costs of this product.

CMS HCPCS Workgroup Preliminary Decision:
1) Use existing code A4565 Slings.

2) Discontinue code L1750 and crosswalk to A4565 effective 12/31/2005.

An existing code, A4565, adequately describes a category of items that perform a function similar to the item in this coding request. This item does not meet Medicare's definition of an orthotic. There are no significant therapeutic distinctions between the category of items described in this A4565 and the item in the coding request. No insurer identified a national program operating need to alter the existing code set to distinguish slings based on the limb it's used for or material used in fabrication. It is not within the jurisdiction of HCPCS code set maintainers to assign fees to codes. Any concerns or inquires regarding reimbursement, such as those raised in your application, should be submitted directly to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private sector health insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim would be filed.

Meeting Agenda Item #4
June 22, 2005
HCPCS Request #05.161

Background/Discussion:

John Neet and Geoffrey Hartzler, M.D. of IntraLuminal Therapeutics, Inc. have submitted a request to establish a code for a radio frequency total occlusion crossing system, Trade Name: The Safe-Cross® Radio Frequency Total Occlusion Crossing Wire. According to the requestor, the Safe-Cross Radio Frequency Total Occlusion Crossing Wire is a sterile, single use guide wire with an intelligent optical guidance capacity and controlled radio frequency micro-ablation technology built into the tip. It is used to cross total occlusions in the coronary and peripheral arteries. With an optical fiber embedded into the guide wire, the system is able to provide guidance feedback to the operator through optical coherence reflectometry.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The item that is the subject of this request is a component of a surgical procedure. The guidewire is included in the procedure code and it is not separately payable. For Medicare OPPS, code C1769 is used for reporting only; although the guidewire is not separately payable. No insurer identified a national program operating need to alter the existing code set to identify this item. For information regarding the surgical procedure coding, contact the American Medical Association CPT division.

Meeting Agenda Item #5
June 22, 2005
HCPCS Request #05.163

Background/Discussion:

Darralyn Alexander of MD Anderson Cancer Center submitted a request to establish a code for an anatomical model, trade name: ClearView® Anatomical View. According to the requester, these anatomic models are life-sized diagnostic models that duplicate the bone and/or soft tissues of an individual patient's anatomy in polymer-type materials. The models are produced using digital information gained from the patient's routine diagnostic computer assisted tomography scan (CT scan) obtained from the treating hospital. These models are used to plan for surgery for obliterated skull and facial bones, spinal deformities, and large bone defects and injuries of the hips, legs and arms and etc. Use of anatomical models enable the surgeons to better plan a procedure and evaluate possible surgical options and problems by evaluating a physical duplication of the anatomy before surgery is initiated and an incision is made. It allows physicians to test a number of surgical options, and choose the best technique to achieve the sought after outcome, with more accuracy and to carry it out more effectively and in less time that might be needed without the use of such a diagnostic and evaluative technology. The applicant states that "no CPT code allows reimbursement" for the cost of the model. The requester is seeking a remedy via HCPCS coding.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The anatomical model is a "diagnostic planning device", as per your application. It is not primarily medical in nature, and therefore not appropriate for identification using HCPCS Level II codes. Inquires concerning the valuation of CPT procedure codes, and whether anatomical models were considered, should be submitted directly to the American Medical Association. For guidance regarding coverage and coding, contact the insurer in whose jurisdiction a claim would be filed. For Medicare, contact the Director of CMS' Division of Outpatient Care. For private sector insurance systems, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Meeting Agenda Item #6
June 22, 2005
HCPCS Request #05.90 A-C

Background/Discussion:

Mark Domyahn of Medtronic submitted a request to establish 3 codes for: A) Single array, implantable non-rechargeable neurostimulator pulse generator, B) dual array, implantable non-rechargeable neurostimulator pulse generator, and C) Implantable extension for neurostimulator systems. According to the requester, Neurostimulation is used to aid in the management of movement disorders, chronic intractable pain, and urinary dysfunction, among other disorders associated with nervous function. An implantable neurostimulation system consists of four components, three of which are implanted into a patient's body, a lead, a power source and a tunneled extension that conducts the electrical pulses between the neurostimulator and the lead. The patient programmer is an external device used by the patient to control the therapy. Neurostimulators can be single-array or dual-array.

A single-array neurostimulator is attached to one lead only. Single array neurostimulators are appropriate for disorders that require a single site of stimulation. The Soletra neurostimulator is used in deep brain stimulation therapy to treat patients with advanced Parkinson's disease and essential tremor. Intrel 3 neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome, and failed back syndrome. Interstim neurostimulator is used to manage urinary retention and the symptoms of an overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone.

A dual-array neurostimulator is attached at two leads. For patients who require bilateral stimulation or stimulation at two separate sites, two leads and two extensions are implanted but only one neurostimulator. Kinetra neurostimulator is used in Deep Brain Stimulation therapy to treat patients with advanced Parkinson's disease and patients with essential tremor. Synergy neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome and failed back syndrome. Synergy Versitrel neurostimulator is used to treat chronic intractable pain.

The extension is implanted into the patient at the same time that the neurostimulator and leads are implanted. Extensions are insulated conductors, which are tunneled subcutaneously in the patient's body between the neurostimulator and the lead. One extension is required for each lead. Models 7489 and Model 7471 are extensions utilized in spinal cord neurostimulation systems used to treat patients with intractable pain in the trunk or limbs. Model 7482 is used in Deep Brain Stimulation therapy and Model 3095 is used with systems for urinary control.

CMS HCPCS Workgroup Preliminary Decision:

#05.90A & #05.90B
As directed by insurer, use existing code C1767 (generator, neurostimulator (implantable); or E0756 (implantable neurostimulator pulse generator); or appropriate CPT code, based on single or dual array.

Existing codes, C1767 or E0756, adequately describe neurostimulator generators which are functionally similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. No insurers identified a national program operating need to alter the existing HCPCS Level II code set to differentiate based on single vs. dual array, or rechargeability. For inpatient use, CPT codes should be used for the procedure and C codes for the implantable items. CPT codes distinguish between dual and single array neurostimulator pulse generators. For ASCs, use CPT codes. For ambulatory clinics, use CPT codes.

#05.90C
Use existing code C1883 adaptor/extension, pacing lead or neurostimulator lead (implantable).

An existing code C1883, adequately describes a category of extensions for neurostimulator systems that function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request.

Meeting Agenda Item #7
June 22, 2005
HCPCS Request #05.11

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a bi-layer foam sleeve composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection. It is approximately 11" in length, looking like an elongated, tapered, oval. The bi-layer foam is sewn into a piece of fabric called Optimer® which is comprised of a blend of cotton, nylon, and two micro fibers called dri-release®, and FreshGuard®. The blended fabric is designed to keep the patient cool, dry by absorbing sweat, and odor free. The sleeve when applied to the site is designed to be able to pick up the body's pulse at the site. Product can be used for the prevention of injuries related to repetitive motion, and also used as a sports performance enhancement product.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "A" code.

A???? Tubular dressing with or without elastic, any width, per linear yard

Use existing code K0620 until new "A" code is effective.

Existing code K0620 and new code A???? describe a category of sleeve or tubular dressings that perform a similar function. There are no significant therapeutic distinctions between the item in this request, and other items included in the code. No insurer identified a national program operating need to distinguish this dressing based on material used in fabrication or multi-layer construction.

Meeting Agenda Item #8
June 22, 2005
HCPCS Request #12

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System with 8% Silver Sodium Hydrogen Zirconium Phosphate. This product is designed to serve as a protective barrier over a wound or burn. The microbisan in the product is designed to keep the site free of infection for up to seven days, while the foam increases and enhances the circulation to the site of treatment, allowing wounds to heal more rapidly. It may also be used in the treatment of pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, and ischemic ulcers.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A6209 foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

Existing code A6209 describes a category of foam dressings that perform a similar function to the item in this request. There are no significant therapeutic distinctions between this product and other items described by A6209. No insurer identified a national program operating need to distinguish this dressing based on multi-layer construction or the silver content in the bandage. Since the FDA has not recognized silver as an antimicrobial, a coding distinction based on such a claim would be inappropriate.

Meeting Agenda Item #9
June 22, 2005
HCPCS Request #13

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System. This product is designed to serve as a protective barrier over a wound or a burn, while providing enhancement of circulation to the site. The product is placed over a properly debrided wound in a manner that does not compress the foam which, gently placed against the surface of the wound and skin, is able to pick up the microcirculation of the capillary bed.

CMS HCPCS Workgroup Preliminary Decision: Use existing codes A6209 through A6211 as appropriate, based on dressing size.

A6209 Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

A6210 Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing.

A6211 Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing.

Existing codes A6209, A6210 and A6211 adequately describe a category of foam dressings which perform a function similar to the item that is the subject of this request. There are no significant therapeutic distinctions between the category of items described in these codes, and the item in the code request. No insurer identified a national program operating need to distinguish this dressing based on multi-layer construction. There was not sufficient peer-reviewed clinical evidence provided with the application to support the claim of amplification of venous flow and decongestion of capillary beds as a result of using this product. A coding distinction based on this unsubstantiated claim would be inappropriate.

Meeting Agenda Item #10
June 22, 2005
HCPCS Request #05.155

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC submitted a request to establish a code for Abrams Wound Care Bandage with 8.5% Silver Sodium Hydrogen Zirconium Phosphate. According to the requester, this wound care bandage is a tri-layer rectangle shaped hydrophilic foam composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection, followed by a third layer of foam which is one 1/8" thick. The third layer of foam is impregnated with a 8.5% silver sodium hydrogen zirconium phosphate with 1% of the total weight as silver. The applicant makes the following claims: The product was lab tested and proven effective for up to seven days warding off infection. The foam is able to stimulate and enhance the micro circulation to the site. The enhancement of microcirculation in the capillary bed results in increase capillary blood flow to the site. This increased flow results in an expedited time to closure of a wound stemming from the increased nourishment to the site of increased blood flow. The site heals from the inside out minimizing scaring while providing the site of treatment a warm, moist environment. The foam is able to absorb excessive wound exudation, while the added layer of foam with silver hydrogen zirconium phosphate is designed to keep the wound free of infection for up to but not to exceed seven days of use. This product is available in 5 standard sizes, and can be custom ordered in other dimensions.

CMS HCPCS Workgroup Preliminary Decision: Use existing codes A6209 through A6211 as appropriate, based on dressing size.

A6209 Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

A6210 Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing.

A6211 Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing.

Existing codes, A6209-A6211, adequately describe a category of foam dressings which perform a function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in these codes and the item in the coding request. The FDA does not recognize the healing properties of silver. No insurer identified a national program operating need to alter the existing code set to differentiate dressings based on multi-layer construction, silver content, or other differences in material used in fabrication. Evidence has not been provided with the application to support the claim of enhanced micro-circulation and expedited wound

closure as a result of the use of this product. Inquiries regarding pricing of this item should be made to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. For private insurance systems, please contact the individual insurance contractor.

Meeting Agenda Item #11
June 22, 2005
HCPCS Request #05.150

Background/Discussion:
Frederick Cahn of BioMedical Strategies LLC submitted a request to establish a unique code for multiple sizes of Collagen Glycosaminoglycan Bilayer Matrix (CGBM), Trade Names: Integra Dermal Regeneration Template, Integra Bilayer Matrix Wound Dressing. According to the requester, CGBM is a bilayer system comprising a dermal replacement layer and a temporary epidermal substitute layer. The dermal replacement layer is a porous matrix of fibers consisting of purified undenatured bovine collagen and chondroitin-6-sulfate with an average pore size between 70 and 200 µm and a void volume greater than 99%. The matrix is cross linked with aqueous glutaraldehyde at acetic pH. The temporary epidermal substitute layer is made of silicone 200 to 300 µm thick and it firmly adheres to the dermal replacement layer. According to the requester C9206 is used for HOPPS. The applicant requests a unique code for use in physician's offices and by private insurers. The applicant states that existing code J7343 DERMAL AND EPIDERMAL, TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER does not describe the products that are the subject of this request because the codes describe dermal and epidermal tissue, whereas CGBM does not contain dermal or epidermal tissue. The applicant also claims that identifying the amount used based on "per square cm" "will under compensate users of smaller sizes". The product is available in 4 sizes: 2x2, 4x5, 4x10, and 8x10. The applicant suggests the assignment of a unit of "25 square centimeters" to the requested new code to be consistent with the unit of 25 square centimeters associated with CPT codes 15342 and 15343.

CMS HCPCS Workgroup Preliminary Decision:
1) Revise language in codes J7340, J7342, J7343, J7344 and J7350 by adding the word "(SUBSTITUTE)" in front of the word "TISSUE".

2) Use existing code J7343, which will be revised in January 2006 to read: "Dermal and epidermal, (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter". The revised language will make it clearer that the item that is the subject of this request is adequately described by this code.

In the descriptor of J7343 code, "dermal and epidermal" refers to substitute layer and therefore, the products that are the subject of this request are adequately described by this code. J7343 describes a category of products that perform a similar function, and the applicant has not demonstrated a significant therapeutic distinction between the category of products described by this code and the items in this code request. No insurer

identified a national program operating need to alter the existing code set to distinguish products in this category based on the variety of sizes of products made available by manufactures. Appropriate multiples or fractions can be entered in the “units” column on a claim form. Inquiries regarding fees associated with this code, such as those mentioned in this application, should be made to the insurer. For Medicare, contact CMS’ Inherent Reasonableness Authority. For private insurance systems, contact the individual contractor. For Medicaid systems, contact the Medicaid Agency in the state which a claim would be filed.

Meeting Agenda Item #12
June 22, 2005
HCPCS Request #05.158

Background/Discussion:
Tom Weaver of the American Optometric Association submitted a request to establish a unique code for solid tint and glass color coating. Presently, solid and gradient tints are both described in existing code V2745 ADDITION TO LENS; TINT, ANY COLOR, SOLID, GRADIENT OR EQUAL, EXCLUDES PHOTOCHROMATIC, ANY LENS MATERIAL, PER LENS. The applicant seeks to separate solid tint from other tints and states in this application that "solid tints are less expensive to manufacture than a gradient tint and usually have a lower reimbursement." According to the requester, solid tint is a treatment that is applied as a coating to a glass or plastic lens or is added to the lens material during the manufacturing process. The tint remains constant throughout the lens. Solid tints reduce light transmission, which improves eye comfort and enhances visual performance. The specific benefits of a tint are its ability to reduce glare, to provide some level of UV protection, to help counteract negative effects of certain lighted environments such as fluorescent lighting in offices. Tints may reduce the effects of certain ocular conditions and enhance the aesthetic appearance of the eyewear.

CMS HCPCS Workgroup Preliminary Decision:
1) Use existing code V2745 (addition to lens; tint, any color, solid, gradient or equal, excludes photochromatic, any lens material, per lens) to identify the tint.

2) Use existing code V2702 (deluxe lens feature) or a "U" modifier, or the "22" modifier if instructed by the insurer, to identify a deluxe lens feature.

Existing code V2745, adequately describes solid or gradient lens tint. Other codes such as V2702, or modifiers, may be specified for used with V2745 by insurers who wish to designate an add-on for a different payment rate. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, please contact the carrier. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to differentiate solid and gradient tints.

Meeting Agenda Item #13
June 22, 2005
HCPCS Request #05.03

Background/Discussion:

Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for an artificial cornea, trade name: AlphaCor™. According to the requester, Alphacor is an artificial cornea made of a biocompatible, flexible, hydrogel material similar to a soft contact lens. It contains central clear zone to provide refractive power and a peripheral skirt or rim made of an opaque porous sponge material which allows fibrovascular ingrowth for long term securing of the device into place. The device is available for those with no natural lens and for those with a lens in the eye.

CMS HCPCS Workgroup Preliminary Decision: Use existing CPT code for the procedure, as directed by insurers.

No insurer identified a national program need to alter the existing code set to identify an artificial cornea used in an implant procedure. For guidance regarding appropriate coding of the implant procedure and the implanted device, contact the insurer in whose jurisdiction a claim would be filed. For Medicare OPPS, CPT codes are used and until December 31, 2005, pass-through code C1818 may also be used in APC 1818. After that, the device may be incorporated into the practice expense. For ASC, use appropriate CPT code and L8699 may be billed separately for the device. For physicians office, use appropriate CPT code and either L8699 or CPT 99070. The volume of procedures in ASCs and physician's offices do not justify the administrative burden of adding a unique code for this device. For coding advice for private insurance systems, contact the individual contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed. For guidance regarding appropriate CPT coding and inquiries regarding whether the CPT will be re-valuated, contact the American Medical Association which maintains and copyrights the CPT code set.

Meeting Agenda Item #14
June 22, 2005
HCPCS Request #05.66

Background/Discussion:

Kevin Corcoran submitted a request to establish a code for intrastromal corneal ring segments, trade name: Intacs. The requester claims that intrastromal corneal ring segments are not included in the ASC facility payment amount as stipulated in MBPM 260.4 (formerly MCM 2265.2), and that the addition of a code is necessary to facilitate Medicare Part B claims in ASCs and also for physician's office and hospital outpatient billing. The requester suggests a new code with the following language "INTRASOMAL CORNEAL RING SEGMENTS". According to the requester, Intacs are intrastromal corneal ring segments designed to reshape the curvature of the cornea to reduce myopia and astigmatism caused by keratoconus. They are clear, thin, psaolymethylmethacrylate (PMMA), crescent shaped, prescription inserts that are surgically implanted in the periphery of the cornea by an ophthalmologist in an outpatient procedure. The placement and dimensions of the Intacs implants help to reshape the cornea to its original, natural shape, thereby normalizing the cornea's architecture. Using proprietary surgical instruments, a small 1.2 millimeter incision is made in the cornea at 70% depth and channels are created for the insertion of the Intacs. Intacs are then threaded into the channels, and the incision is closed using 10-0 suture. Surgical treatment of keratoconus with Intacs is reversible and less invasive than penetrating keratoplasty or corneal transplant.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a HCPCS Level II code. Refer to AMA. Use existing CPT codes as directed by the insurer in whose jurisdiction a claim would be filed.

Your request for a code has not been approved because it is inappropriate for inclusion in the HCPCS Level II code set. This item is not a prosthetic or a replacement. The CMS HCPCS Workgroup suggests that you independently approach the AMA for valuation of intrastromal corneal ring segments and CPT coding guidance, or an inquiry regarding inclusion of your product under category III of the CPT code set for emerging technologies.

Meeting Agenda Item #15
June 22, 2005
HCPCS Request #05.68

Background/Discussion:

Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for a capsular tensular ring, trade name: Morcher Capsular Tension Ring. The requester claims that capsular tension rings are not included in the ASC facility payment amount as stipulated in MBPM 100-4, 260.4 (formerly MCM 2265.5); however there is a provision for reimbursement for HOPPS as an incidental component of APC 246. Requester is seeking a new HCPCS code to facilitate ASC claims under Medicare Part B, and suggests the following language: "CAPSULAR TENSION RING". According to the requester, capsular tension rings consist of an incomplete loop made out of a flexible polymethyl methacrylate filament with eyelets at each end. The device is indicated for the stabilization of the human crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness, secondary zonular weakness, zonulysis, pseudoexfoliation and Marchesani Syndrome.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a HCPCS Level II code. Use existing CPT codes. Refer to AMA for CPT coding guidance.

Your request for a code has not been approved because the item that is the subject of your request is included as part of a surgery and it is not appropriate for inclusion in the HCPCS Level II. The CMS HCPCS Workgroup recommends that the applicant independently approach the AMA for CPT coding guidance. This product does not meet the definition of a prosthetic. ASC payment does not accommodate this item separately.

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Meeting Agenda Item #16
June 22, 2005
HCPCS Request #05.159

Background/Discussion:

Anne Sather of Hypoguard submitted a request to establish a code for an express blood glucose monitoring system, NewTeK™. According to the requester, NewTek is a self-contained blood glucose monitoring system with 100 pre-loaded, pre-calibrated test strips included in the device. The device is disposed of after 100 uses. NewTek reads a patient's blood glucose level with its pre-loaded, pre-calibrated test strips. The user simply pulls a lever to dispense a test strip, places their capillary blood sample on the strip, and waits 15 seconds for test results. Once the blood glucose level is read, the patient ejects the test strip from the meter by pushing the lever backwards. NewTek is used for persons with diabetes to aid in monitoring the effectiveness of diabetes control by quantitatively measuring the glucose in a fresh capillary whole blood sample. The applicant describes this product as a unique self-contained blood glucose monitor and 100 test strips in one device. Therefore, according to the applicant, codes that separately describing only the test strip or only the monitor do not adequately describe this product. The applicant acknowledges that this product does not meet Medicare's definition of DME and that for Medicare, A9270 is the appropriate code. The applicant, however, is seeking a code for use by state Medicaid agencies and Private Insurers.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "E" code.

E???? Home glucose monitor, includes strips, disposable, each.

Appropriate code assignment is a made by the insurer in whose jurisdiction a claim is filed. For Medicare, A9270 (non-covered item or service) is the appropriate code, and new code E???? will be available for use by non-Medicare insurers if they choose to designate it to describe this item. To confirm appropriate coding for private insurance systems, contact the individual private insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Meeting Agenda Item #17
June 22, 2005
HCPCS Request #05.160

Background/Discussion:
Patty Curoe of Medtronic Diabetes (MiniMed) has submitted a request to establish 3 separate codes to reflect the 3 components of the Guardian® Telemetered Glucose Monitoring System. The applicant suggests the following language for the 3 requested codes: 1) "Sensors; interstitial continuous glucose monitoring system, per sensor"; 2) "transmitter; interstitial continuous glucose monitoring system"; 3) "monitor; interstitial continuous glucose monitoring system". According to the requestor, the Guardian System is a glucose monitoring system that continuously records glucose values measured in interstitial fluids such as those in subcutaneous tissue. The patient inserts a subcutaneous sensor under the skin which records glucose values every ten seconds and transmits results wirelessly to a small external monitor. The monitor is designed to alert the patient when glucose values go above or below the target ranges prescribed by the physician.

CMS HCPCS Workgroup Preliminary Decision: No new code.

There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. Your application reported used of a very limited number of units on a trial basis, in pilot programs. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, contact the carrier in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. Use of miscellaneous codes is not appropriate unless directed by the insurer. No insurer identified a national program operating need to alter the existing code set to describe this item at this time. Applicant may wish to submit another request in a subsequent coding cycle if the sales volume increases significantly.

Meeting Agenda Item #18
June 22, 2005
HCPCS Request #05.165

Background/Discussion:

Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for unit dose Stannous Fluoride Concentrate, Trade Name: MedOral Anti-microbial Fluoride Rinse. According to the requestor, MedOral-Anti-Microbial Fluoride Rinse is a two-part 1oz. dose of 0.63% Stannous Fluoride solution. The rinse acts on gram negative biofilm bacteria colonies in the oral cavity, when used three times daily as a preventative. The applicant claims that daily use diminishes oral pathogens associated with a large variety of systemic diseases and that the therapeutic goal of MedOral Fluoride Rinse is to minimize potential negative influences of oral pathogens in conditions such as cardiovascular disease and diabetes as well as pulmonary disease. It is considered an over the counter drug supplied as a unit-dose, self contained packaging design that can be administered by an attending nurse or nurse's aid.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9150 (non-prescription drug) or the appropriate NDC code, based on instructions provided by the insurer.

Existing code A9150 and NDC codes are available for assignment as individual insurers deem appropriate. Code assignment and coverage policy is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9150 is the appropriate code. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing HCPCS code set to specifically identify Stannous Fluoride. Such a code would be redundant of existing NCD codes.

Meeting Agenda Item #19
June 22, 2005
HCPCS Request #05.166

Background/Discussion:

Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for MedOral Dry Mouth Treatment, Trade Name: MedOral Dry Mouth Treatment. According to the requestor, MedOral Dry Mouth Treatment is a non-aerosol spray that moistens the oral cavity and helps replenish saliva in the patients with dry mouth symptoms. The product is sprayed in the mouth distributed by the tongue and reapplied, as needed approximately every one to two hours. It is indicated in a broad population of patients, including but not limited to those with medication induced dry mouth, xerostomia, diabetes, cancer treatment patients, and others. It is primarily an oral aid in rewetting the oral mucosa surfaces.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9150 non-prescription drug.

Existing code A9150 is available for assignment as individual insurers deem appropriate. An NCD code may also be available. Code assignment and coverage policy is made by the insurer in whose jurisdiction a claim is filed. For Medicare, A9150 should be used. For private sector health insurance systems, please contact the Medicaid Agency in the state in which a claim is being filed. No insurer identified a national program operating need to alter the existing HCPCS code set to specifically identify dry mouth treatment.

Meeting Agenda Item #20
June 22, 2005
HCPCS Request #05.181

Background/Discussion:

Rebecca Fancher of Protex Medical Products, Inc. submitted a request to establish a code for a limb cover and torso coverings, trade name: Protex Limb Protectors and Body Covers. According to the requester the Protex product line includes limb protectors that are protective coverings for the arms and legs, and two torso coverings, that help pressure the integrity of a wound, dressing, surgery site, cast, vaccine, IV, PICC line, venous procedures, burns, rashes or any other area of concern that needs to be protected from damaging moisture or other contaminants, especially during a bathing process. These covers fit over and seal off the area of concern to allow the wearer to resume and maintain normal bathing routines or daily activities, using a simple one-step process.

CMS HCPCS Workgroup Preliminary Decision: No new code.

Code assignment and coverage policy is made by the insurer in whose jurisdiction the claim is filed. For Medicare, there is no existing benefit category for this item and A9270 NON-COVERED ITEM OR SERVICE is the appropriate code, and the use of miscellaneous codes for this item is inappropriate. For coding guidance for private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe limb protectors or body covers.

Meeting Agenda Item #21
June 22, 2005
HCPCS Request #182

Background/Discussion:
Steve Cooley of Welcon Medical Products submitted a request to establish a code for a pillcrusher, trade name: Welcon Pillcrusher™ Enteral Irrigation Syringe. According to the requester, the PillCrusher is an "all-in-one" system for the crushing, dissolving, and delivery of soluble solid medications in water. It is designated for use with patients using enteral feeding tubes or who have difficulty swallowing. The solid medication is placed into the syringe and then crushed into a powder form by pressing and rotating the syringe piston against the medication. Sterile water is then drawn into the syringe and the syringe is shaken or agitated to completely dissolve the medication powder. This medicated solution is then injected through the enteral feeding tube or administered orally to deliver the proper medication and dosage amount to the patient.

CMS HCPCS Workgroup Preliminary Decision: Use existing code B4034 Enteral feeding supply kit; syringe, per day.

Existing code B4034 adequately describes enteral irrigation syringes. The pill crusher component of this product is considered a convenience item. No insurer identified a national program operating need to alter the existing code set to describe a pill-crushing enteral irrigation syringe. There is no Medicare benefit category for the pill crusher component. For Medicare, use code B4034 to describe the syringe and A9270 (NON-COVERED ITEM OR SERVICE) for the pill crusher. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Meeting Agenda Item #22
June 22, 2005
HCPCS Request #05.183

Background/Discussion:

Eric Dixon of EProducts, Inc. submitted a request to establish a code for a non-invasive drinking apparatus for measuring and managing fluid intake, trade name: DigiStraw. According to the requestor, DigiStraw is a non-invasive drinking apparatus for measuring and managing fluid intake. It includes a disposable straw for the user to draw fluid. A flow sensor is attached in-line to the straw for measuring the fluid flow rate. An electronic microprocessor is connected to the flow sensor to convert the flow rate to volume. A display enables the patient to view the total amount of liquid consumed and set threshold amounts. A total amount of fluid can be set as an alarm threshold. DigiStraw is powered by two 3 volt batteries. This device is targeted at managing interdialytic fluids for hemodialysis patients, dehydration management in elderly and cardiac patients. DigiStraw can be mounted on most cups, glasses or cans. As the user sucks on the straw, flow sensor measures the flow of fluid through the straw and micro-controller converts the flow signal to volume and adds the measured volume flow to a stored volume, and displays the cumulative volume on display. When turned off, the total volume is stored in the micro-controller unit reset.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The DigiStraw is not diagnostic or therapeutic and is not primarily medical in nature. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is being filed. For Medicare, there is no existing benefit category and A9270 (NON-COVERED ITEM OR SERVICE) is the appropriate code. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe this item.

Meeting Agenda Item #23
June 22, 2005
HCPCS Request #05.25

Background/Discussion:

Linda Brown of In HomeCare Hair Shampooing Co, LLC submitted a request to establish a code for a hair shampooing chair, trade name: In Homecare Hair Shampooing Chair. According to the requestor, In Homecare Hair Shampooing Chair is a shampooing chair that is specifically designed to provide a way to safely, conveniently, and effectively shampoo hair in the home, hospital, nursing homes, health care facilities, or when traveling. The main feature of the chair is the adjustable semi circular neck rest that is designed to support and stabilized the neck while shampooing the hair. The main purpose of the hair-shampooing chair is to protect the eyes, and ears, from suds and water during shampooing and rinsing by allowing water to freely flow away from the face. The main advantage of the chair is that the person would get a relaxing shampooing in the home, hospital, nursing home, or any other healthcare facility. The hair shampooing chair can be placed at the sink to shampoo hair, or placed into the bathtub to bathe the person and shampoo hair at the same time.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The product is not primarily medical in nature. Code assignment and coverage policies are determined by the insurer in whose jurisdiction a claim is filed. For Medicare, this product does not fit any benefit category, and the item is not covered, therefore the appropriate code is A9270(non-covered item or service). For coding guidance for a private insurance system, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.